European Medicines Agency

London, 17 September 2007
Doc. Ref.: EMEA/416463/2007

Mr. Anders Jørgensen
Dr. Peter C Gøtzsche
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Denmark

Dear Sirs,

Thank you for your fax of 24 August 2007, in which you request that the Agency reconsiders its decision of 20 August 2007 concerning your application for access to the clinical study reports and protocols for placebo-controlled trials of anti-obesity drugs (orlistat and rimonabant) submitted to the EMEA for marketing approval. Your appeal has been handled in accordance with the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents. As indicated in the title, these rules implement the principles and procedures established in Regulation (EC) 1049/2001 to documents held by the EMEA.

We regret to inform you that the documents you requested come under the system of exceptions set out in the implementing rules, and therefore cannot be released.

The exception that applies to the documents you requested is listed in Article 3.2(a) of the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents, which refers to commercial interests of a natural or legal person, including intellectual property.

However, if you wish to appeal against this decision, the legal remedies open to you are either to lodge a complaint to the European Ombudsman or to institute Court proceedings against the Agency, under Article 195 or 230 of the EC Treaty, respectively.

Considering the concerns expressed in your letter with regard to the EMEA transparency policy we would like to emphasise that the position of the EMEA at the present time is not to disclose original data submitted as part of application dossiers; however such data as the clinical trials you are referring to are considered and assessed by the EMEA Scientific Committee for Human Medicinal Products and the outcome of such scientific discussions is published in the EMEA website as part of the European Public Assessment Report for the products concerned.

Furthermore we would like to point out that the European Medicines Agency works in collaboration with the network of National Competent Authorities and its role is to monitor the safety and efficacy of all medicines within the scope of the Agency's mandate. On this regards systems are in place to ensure that the balance of benefits and risks of all authorised medicinal products is under constant review and that actions are taken where appropriate to protect public health.

Yours sincerely,

Thomas Lönngren
Executive Director

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